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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,747	12/03/2001	Shimon Slavin	02/23156	1863

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EXAMINER	
EWOLDT, GERALD R	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,747	SLAVIN, SHIMON	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-64* is/are pending in the application.

4a) Of the above claim(s) *22-26 and 35-38* is/are withdrawn from consideration.

5)☐ Claim(s) *20-21, 27-34, 39-64* is/are allowed.

6)☒ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 20, 21, and 27-34, and newly added Claims 39-64, are being acted upon.

2. Claims 22-26 and 35-38 stand withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b) as being drawn to nonelected species.

3. Applicant is again advised that a handwritten change has been found at page 50, line 6 of the specification. Accordingly, this application is not a Continuation of parent application 08/735,496, but rather a Continuation-in-Part. A new declaration reflecting said change is required.

4. The first line of the specification must be amended to disclose all of the updated priority data.

5. In view of Applicant's amendment, filed 1/06/04 the previous rejections under the second paragraph of 35 U.S.C. 112 have been withdrawn. In particular note that Applicant has amended the claims to remove all of the terms that necessitated the rejections. Also, in view of Applicant's amendment, the previous rejections under 35 U.S.C. 103(a) and the double patenting rejections have been withdrawn. In particular note that Applicant has amended the claims to recite limitations, e.g., "at least partial engraftment" of donor lymphocytes and a second stem cell transplantation (allogeneic after autologous) not taught by the prior art. Finally, the previous rejection under first paragraph of 35 U.S.C. 112 has been withdrawn given Applicant's withdrawal of the limitation of Claim 29 requiring the use of the patient's own fetal tissue.

6. The following are new grounds for rejection necessitated by Applicant's amendment.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 20, 21, and 27-34, and newly added Claims 39-64, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the phrase ""minimal graft versus host disease" is vague and indefinite as it has not been defined in

the specification. Note that Applicant has previously argued that the specification adequately defines "clinically mild graft versus host responses" and in said argument indicated that "Such "minimal" GVHD responses will be clearly understood by the ordinarily skilled artisan as being the same as "mild" GVHD responses." Applicant cites page 36, line 16 in support.

It is the Examiner's position that, Applicant's "very strong opinion" not withstanding, the specification fails to adequately define the instant term. The cited line discloses, "On day 14 following allogeneic BMT, the patient showed minimal signs of acute GVHD with involvement of skin and oral cavity." It is unclear to the Examiner how Applicant can consider this disclosure to comprise a definition. The specification continues, "There was no intestinal or liver involvement. Since then the patient has continued to experience grade I/II mucocutaneous
GVHD, partially controlled with steroids and cyclosporin A." It is the Examiner's position that these sentences also fail to define "minimal GVHD".

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 20, 21, and 27-34, and newly added Claims 39-64 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, independent Claim 20:

"A method of treating a human cancer patient, the patient having undergone a malignant cell debulking procedure associated with at least partial loss of hematopoiesis and having further undergone autologous stem cell transplantation incident to the debulking procedure, the patient being at risk of disease relapse due to a population of residual malignant cells that may remain viable in

the patient following the debulking procedure, the method Comprising:
(a) administering to the patient a dose of lymphocytes derived from a lymphocyte donor in a regimen selected so as to cause at least partial engraftment of said lymphocytes in the patient, said lymphocyte donor being allogeneic with the patient; and
(b) administering to the patient a dose of stem cells derived from a stem cell donor in a regimen selected so as to cause minimal GVHD in the patient, said stem cell donor being allogeneic with the patient, thereby treating the cancer in the patient",

is not supported by the specification or claims as filed.

Applicant indicates that support for the new method is found at pages 37-38, i.e., the disclosure regarding Patient No. 8. Applicant is advised that the disclosure of a specific example is insufficient to support the generic independent claim. For example, the claim would encompass the treatment of any cancer patient, the example, however, discloses only the treatment of a 36 year old non-Hodgkin's lymphoma patient. Also note all of the limitations of the dependent claims now also comprise new matter. For example, Claim 40 would encompass any cancer patient in partial remission. The specification, however, discloses only the 36 year old non-Hodgkin's lymphoma patient (Patient No. 8). Also note that method as now claimed is not the method disclosed as the generic method of the specification. See, for example, the specification at page 18 wherein it is taught that the claimed method is intended to encompass only temporary engraftment because permanent engraftment would put the patient at risk of severe GVHD. Further note the disclosure at page 23 of the specification wherein it is disclosed that engraftment of immunocompetent T lymphocytes from a donor could cause GVHD which could be "stormy and lethal". Yet new Claim 41 recites a method encompassing "full engraftment" of the donor lymphocytes. Accordingly, all of the claims under examination are now considered to comprise new matter.

11. No claim is allowed.

12. Applicant is advised that should the invention of the previous claims be reintroduced the reintroduction of the previous rejections might be required. However, said reintroduction would be considered a new issue After Final.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

15. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

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3/15/04
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